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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,198	04/04/2005	Yoko Matsuzawa	040894-7204	9611

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MORGAN LEWIS & BOCKIUS LLP
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WASHINGTON, DC 20004

EXAMINER

AUDET, MAURY A

ART UNIT	PAPER NUMBER
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1654

MAIL DATE	DELIVERY MODE
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12/13/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/530,198

Applicant(s)

MATSUZAWA ET AL.

Examiner

MAURY AUDET

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2007.
- 2a) ☐ This action is FINAL.
- 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All
 - b) ☐ Some *
 - c) ☐ None of:
 - 1. ☐ Certified copies of the priority documents have been received.
 - 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 6/26/07.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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DETAILED ACTION

Applicant's amendment and response are acknowledged. Claim 14 is pending and examined on the merits. Applicant argues the amended claim 14, incorporating certain teachings of previous claims 1-13 into a single claim, is no longer taught by Applicant's earlier works. The Examiner has applied a secondary reference (Tsilosani et al. (US 6,743,638), directed to the gaps which Applicant has cited (spherical in shape, containing pyranine). Thus, based on the new recitation to more distinctly show the motivation to arrive at the originally presented claimed subject matter, the present action is being sent NON-FINAL.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by either Kogiso et al. (US 6,136,956, issued 10/24/00, two inventors in common with the present application) or Agency of Ind. Science & Techn. (now JP-B-3012932 Patent, 12/17/99, application JP 11-322787, cited in IDS of 4/4/05) - both discussed collectively under Kogiso et al. in view of Tsilosani et al. (US 6,743,638). The rejection is virtually identical, other than the recitation of Tsilosani et al.

It is noted that Applicant's earliest effective priority date is 10/7/02, greater than one year after the '956 patent issued.

Kogiso et al. teach:

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1) the identical compound of formula I (entire document). As the present specification page 1-2 recites: "[i]t is described, for example, in Japanese Patent No. 3012932 and Chem. Comm., 1998, pp. 1791-1792 that the above compound forms a nano-scale fiber having a width of about 10 to 30 nm when an aqueous alkaline solution of the compound is gradually acidified"].

Kogiso et al. ;

2) linear products, namely fibers and fibrous assemblies, comprising the same; as well as spherical products, the easier to make product as discussed (col. 1, lines 21-34); and

3) a method of making the same using a substrate having hydrophilicity (e.g. glass vial), alkali metal salt, precipitated under a weakly acid atmosphere (Example 1 ; col. 2, lines 21-31; claims 5-7).

Specifically, the background on the art's processing of the easier made fine spherical versions of the '956 patented fibers/fibrous assemblies of Kogiso et al. is described in Kogiso et al. at col. 1, lines 21-34 and col. 3, lines 29-53:

"... well known, fibrous assemblies of a peptide lipid are widely employed in many applications, besides the applications as a drug delivery system or an adsorbent, in the fields of medical and pharmaceutical sciences as a bioadaptable material, in the fields of electronic and information-processing technologies as a material of microelectronic parts, in the fields of food industries, agriculture, forestry and fiber industries as an emulsifying agent, stabilizer, dispersing agent or moisturizing agent and so on.

In the prior art, spherical assemblies obtained from a natural phospholipid or so-called liposomes are known among molecular aggregates formed from a phospholipid. Such a

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spherical assembly is usually prepared by the thin-film method, thermal dispersion method, cholic acid method or reversed-layer evaporation method (see, for example, "Seitaimaku Jikkenhou" (Experimental Methods for Biomembranes), volume 2, page 185, published by Kyoritu Shuppan Co.).

Each of these prior art methods, however, requires extremely high skillfulness. In addition, the *molecular aggregates* obtained by these methods are limited to a *monolayered vesicle* or *spherical multilayered vesicle* and long fibrous assemblies cannot be prepared thereby. On the other hand, several method are disclosed, for example, in Journal of the American Chemical Society, volume 119, pages 9120-9124 (1997) for the preparation of a fibrous assembly from a synthetic amphiphilic compound in water. Each of these methods, however, is a method in which fibrous assemblies are obtained by spontaneous *precipitation* or crystallization from a hot concentrated *aqueous solution* containing an *amphiphilic compound* so that the yield of the product is necessarily limited.

[]

The various reagents, i.e. amino group-protective agent, carboxyl group-protective agent and coupling agent, and the procedures in the above described reaction can be conventional and freely selected from those used in the prior art for peptide synthesis. The intermediate peptide compounds formed in the course of the reaction can readily be isolated and purified by washing the reaction mixture with an acid or alkali aqueous solution followed by recrystallization or reprecipitation.

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The fine fibrous assembly of the invention is obtained from an aqueous solution of an alkali metal salt of the above described bola-form peptide lipid compound by causing precipitation thereof in a crystalline form.

The only thing Kogiso et al. does not expressly teach is that said fine spherical products have "uniform molecular orientation" or the word "microcapsule" (and that said microcapsule can encompass a substance having hydrophilicity, e.g. glass?). Hence the present rejection is made under 103, rather than 102, as expressly anticipated.

Tsilosani et al. teach nanoparticles/microcapsules/spherical liposomes of varying size, wherein "In the embodiment of FIG. 1, a particulate containment means such as a liposome (1) contains signal generating agents (2) which generate signal in response to the presence of an ion such as H⁺. Suitable agents (2) are therefore pyranine" (see Fig. 1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have made a "uniformly oriented" and/or "microcapsule" spherical version, comprising pyranine as the visible agent therein, of the fiber/fibrous assemblies comprising compounds of Formula 1 in Kogiso et al., because Applicant's earlier work expressly states that making the spherical versions of such constructs is easier and known and the advantageous teachings of Tsilosani et al. indicate that spherical bodies of minute proportion comprising pyranine were known in this same art. And as previously stated, it was the linear, fiber versions that posed enablement & development issues, not spherical constructs, which were well known in the art to have uniform molecular orientation and be used in the biomedical fields as microcapsules, which

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encapsulate water-attracted compounds/molecules. Thus, even though a secondary reference to the same need not have been necessary or further expounding necessary, as evident by the recited specification pages above, from Kogiso et al., such has not been provided to clarify the record.

Thus, from the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

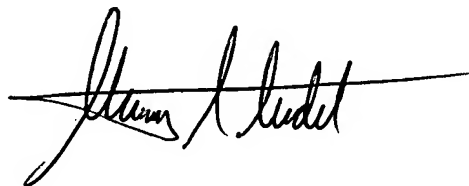
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 12/7/2007

A handwritten signature in black ink, appearing to read "Maury Audet", with a long horizontal stroke extending to the right.

MAURY AUDET
PATENT EXAMINER